Bioanalysis Solutions

Health Inspired, Quality Driven.

SGS

Your Bioanalytical Testing Partner

With over 30 years of experience and operating out of our GLP/GCP compliant laboratories. SGS has the expertise to both develop assays from scratch and to support large scale routine sample analyses, from regulatory pre-clinical (toxicology) to early and late clinical studies (Phase I to IV).

Explore the sections of this brochure

Services

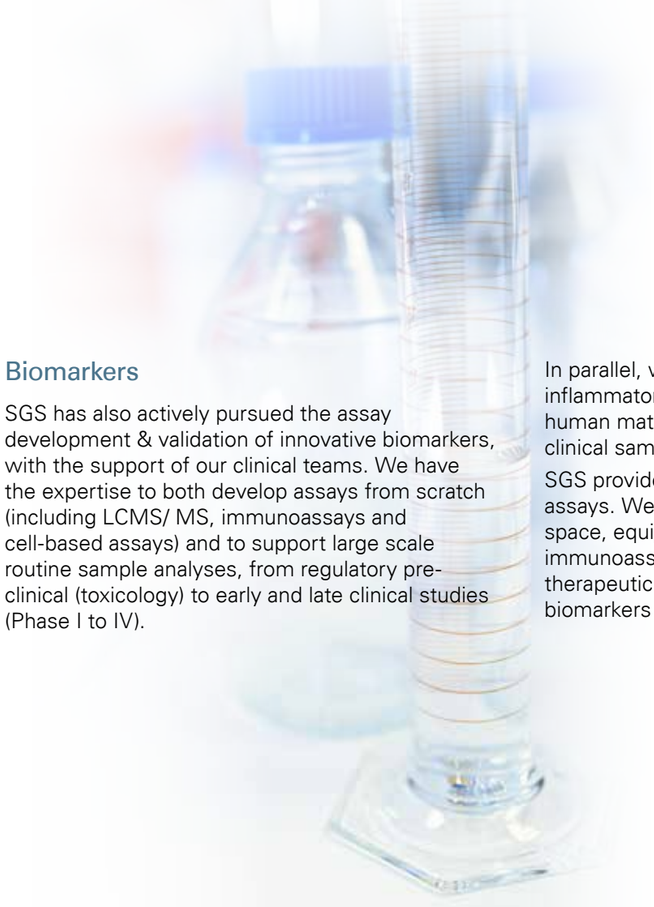
SGS Health Science can provide bionanalytical testing for drug development from preclinical to early and late clinical phases

- Method transfer, development and validation for small molecules, biologics, biosimilars and biomarkers.
- PK bioanalysis (small molecules, biologics, biosimilars)
- PD bioanalysis (soluble and cellular biomarkers)
- Immunogenicity testing (screening, confirmatory, titration characterisation and neutralising anti-drug antibody assays)
- ELISA and multiplex assays for parent drug, metabolites, biomarkers
- Cell-based assays (cellular biomarkers, receptor occupancy, neutralising anti-drug antibody assays, immunophenotyping)
- Hybrid approach LBA/LC-MS/MS

Continuous Focus on Development

A dedicated group evaluates assay requests from a strategic and scientific point of view. SGS offers more than 700 validated methods that are ready for use with very short lead time. Validation criteria follow guidelines from

- FDA: Bioanalytical method validation (2018) & Immunogenicity (2019)
- EMA (2011) for GLP compliance
- OECD Principles of Good Laboratory Practice (1997) for GLP compliance
- EMA Bioanalytical method validation (2011) & Reflection Paper (2012) for the GCP compliance



Biomarkers

SGS has also actively pursued the assay development & validation of innovative biomarkers, with the support of our clinical teams. We have the expertise to both develop assays from scratch (including LCMS/ MS, immunoassays and cell-based assays) and to support large scale routine sample analyses, from regulatory pre-clinical (toxicology) to early and late clinical studies (Phase I to IV).

In parallel, we have validated several multiplex inflammatory panels (cytokines/chemokines) in human matrices, methods readily available for clinical sample analysis.

SGS provides services on a large list of biomarker assays. We have increased our capacity (lab space, equipment and staff) to develop multiplex immunoassays for biomarker screening by therapeutic area. We also invested in platforms for biomarkers analysis under GLP/GCP environment.

Large Capacity for Rapid Results and Data Delivery

In order to support the bioanalysis of various classes of compounds, SGS offers a large range of techniques and methods, providing fast turnaround analysis of large number of samples.

- Mass spectrometry: 31 LC-MS/MS
- Waters equipment
- Immunoanalysis: ELISA, RIA, ECLIA measurements for routine analysis of a variety of molecules including therapeutic proteins, monoclonal antibodies (mAb), antibody-drug conjugates (ADCs), peptides and biosimilars.
- Automated sample preparation using robotics or turbulent flow technology (Cohesive)
- Large sample storage capacity combined with sample tracking systems using various types of barcodes

Innovative Technologies

- Customized immunoassay method development and validation for New Biological Entities to support Pharmacokinetics (PK) and Immunogenicity (ADA) studies
- Biomarker method development and screening by Multiplex Immunoassays
- Peptide quantification
- Complex LC-MS/MS methods for multiple biomarkers detection in a single sample
- Rapid plasma protein binding determination by equilibrium dialysis coupled with LC or LC-MS analysis
- Dried blood spot samples analysis by LC-MS/MS
- Hybrid approach LBA/LC-MS-MS for NBEs
- Flow cytometry capabilities operating in a GCP environment (FACS CANTO & Verse)
- Clotting and chromogenic assays (Diagnostica Stago)

CAPABILITIES					
	EUROPE				ASIA
COUNTRY	BELGIUM	FRANCE	GERMANY	SWITZERLAND	CHINA
Method development/ transfer	•	•	•	•	•
Method validation	•	•	•	•	•
PK Bioanalysis	•	•	•	•	•
PD Bioanalysis (soluble and cellular biomarkers)	•	•	•		•
Immunogenicity testing		•		•	•
Cell-based assays		•		•	•
Hybrid approach LBA/ LC-MS/MS	•	•		•	•
Discovery (PK, ADA, Immunotox)		•			•

Services – Bioanalysis per type of molecules

Biotherapeutics

Ligand-Binding Assays

- Method Development/transfer/validation
- PK Bioanalysis
- Immunogenicity
- Biomarkers (soluble)
- Discovery (PK, ADA, Immunotox)

Hybrid approach LBA / LC-MS/MS

- PK Bioanalysis

Cell-Based Assays

- Neutralising Anti-Drug Antibodies
- Functional assays
- Biomarkers (cellular)

Small Molecules - Peptides

Mass Spectrometry

- Method development / transfer / validation
- PK Bioanalysis
- PD Bioanalysis
- Discovery

Cell & Gene, mRNA, CAR-T Therapy

qPCR

- Method development/transfer/validation
- PK Bioanalysis (i.e. mRNA quantification, CAR-T cells)
- Immunogenicity
- Biomarkers (soluble)
- Viral Vectors

Hybrid approach LBA / LC-MS/MS

- Biomarkers (cellular)

Cell-Based Assays

- Immunophenotyping (i.e. T-cell Activation)
- Target Protein Expression
- Biomarkers (cellular)
- Detection of therapy-produced cells (i.e. CAR-T, gene therapies)

Clinical Trial Laboratory Testing

At SGS we offer you a large variety of laboratory tests for your clinical development: from routine safety testing, bioanalysis to customized testing solutions. SGS is your experienced partner to support you in all laboratory related aspects of clinical development.

From protocol design through development up to market our experts will deliver the highest quality and customized laboratory solutions. As central lab we provide your clinical trial sites with harmonized, visit-specific, collection kits. This will provide a solid basis for high quality data. Afterwards our highly motivated and experienced project managers will take care of the sample logistics, considering sample stability for determining the most appropriate temperature range and longest turnaround time for conducting the best possible and most cost-efficient transports. After reception of the samples at our state-of-the-art equipped and qualified facilities, which is in alignment with all clinical trials requirements, samples are either stored at the required temperature or immediately analyzed. From routine safety lab testing through immunologic tests, biomarkers, genetics to bioanalysis we will provide you with high quality tests and deliver reliable results. Last but not least our client-oriented data managers will customize lab reports and data transfers can seamlessly be integrated into the clinical database. While each service can be provided within full project service, a standalone service is of course also available.

SGS is your global central lab partner of choice providing fully-integrated, or standalone, multi-disciplinary central laboratory services to support your clinical development needs.

Quality Management

SGS complies with the requirements of all global regulatory authorities necessary for approval.

Our 6 layer system:

- Global quality handbook
- Global policies
- Global SOPs
- Local quality handbook
- Local SOPs
- Site quality documents

Based on current guidelines and quality principles:

Certifications on local levels

- GMP
- GLP/GCP

Accreditations on local levels

- ISO 17025
- ISO 9001
- WHO (prequalification scheme)

We work according to standards issued by regulatory authorities, including:

- US FDA
- EMA/MHRA
- Health Canada
- Swiss Medic
- ANSM
- PDMA (Japan)

Harmonized Regulatory & Quality Management System

CAPABILITIES					
	EUROPE				ASIA
COUNTRY	BELGIUM	FRANCE	GERMANY	SWITZERLAND	CHINA
Quality Management System	GMP/GLP/ GCP	GLP/GCP	GCP/GLP	GMP/GLP/GCP	GLP
ISO Standard	17025	-	17025	17025	17025
US-FDA Registered	•	•		•	
US-FDA Inspected	•	•	•	•	

Highest Quality Standards

- GLP/GCP compliant bioanalytical sites
- Each site is periodically inspected by the relevant local and international agencies
- 21 CFR Part 11 compliance program
- Independent QA group (project and facility audits and GLP training)

Delivering Sustained Excellence

SGS has always been at the forefront of bringing excellence into the business environment.

With OneVision, our global digitalization initiative to create a single, integrated network of testing laboratories, the SGS Health Science global network of laboratories delivers a more comprehensive service to their customers, adding value and delivering faster turnaround times.

Utilizing the latest technologies, OneVision implements standardized record-keeping processes in all offices and laboratories around the globe. This means, wherever a customer is in the world, they are guaranteed the same high-quality service.

TRANSFORMATION

Implements a fully digitalized global network that interconnects systems and laboratories to create a modern, forward-looking business structure.

HARMONIZATION

Establishes a standardized digital record-keeping platform across the SGS global network to reinforce our commitment to quality service.

OPTIMIZATION

Standardizes all network data inputting and streamlines processes to generate greater efficiencies, improve turnaround times and deliver better customer service.

DIGITALIZATION

Creates a single, global digitalized laboratory network with improved communications between the SGS network and its customers.

SUSTAINABILITY

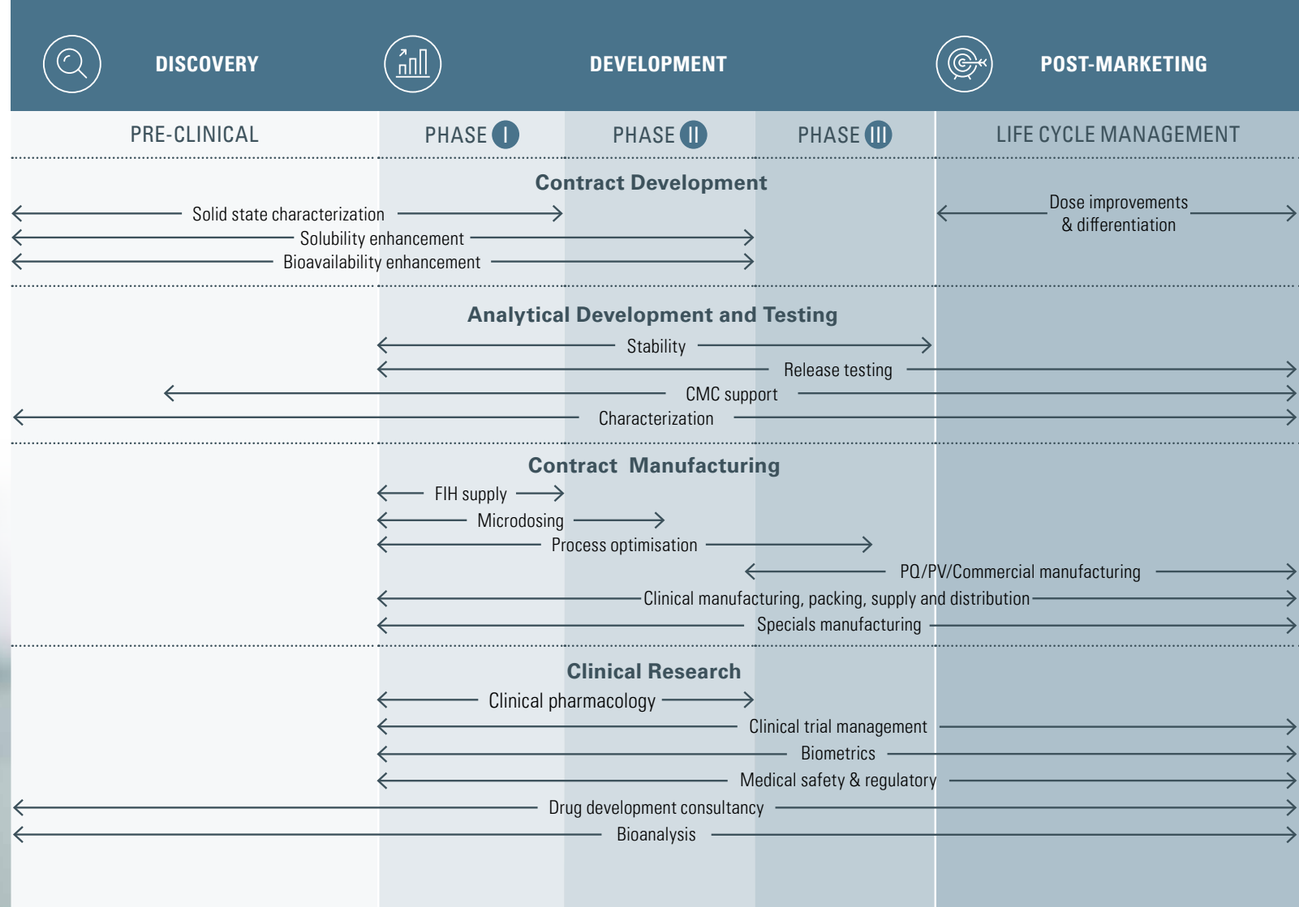
Reduces environmental impact through digitalization, lessening the need for paper and storage while delivering greater efficiencies.

BUSINESS EXCELLENCE

Delivers optimal business evolution through high-tech system adoption, enabling continuous network improvements.

Scope of SGS Health Science

Next to bioanalysis solutions SGS Health Science delivers industry-leading contract development and manufacturing (CDMO) and analytical development and testing to support you every step of the way as you deliver first-class, fully compliant biopharmaceutical and pharmaceutical drugs, clinical research, and medical devices.



Health Science

Health Inspired,
Quality Driven.

Contact us

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WHEN YOU NEED TO BE SURE

SGS